REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated July 24, 2006 are respectfully requested.

I. Amendments

Claims 1 and 18 are amended for clarity.

Claim 9 is amended to correct an obvious typographical error.

No new matter has been added by way of these amendments.

II. Rejection under 35 U.S.C. §112, second paragraph

Claims 1, 2, 5, 6, 8, 9, 11-14, 16, 18, 23, 25, 26, and 30 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner had five specific rejections, which are set forth and addressed below.

1. Claims 1, 2, 5, 6, 8, 9, 11-14, 16, 18, 23, 25, 26, and 30

The Examiner objected to the language "the virus is inactivated" for antecedent basis. Claim 1 is amended to provide proper antecedent basis for the language.

2. Claim 1 and claims dependent thereon

The Examiner objected to the claim as allegedly incomplete for omitting essential structural cooperative relationships of elements. Specifically, the Examiner states that the omitted structural relationships are inactivating the genome of a herpes virus. Claim 1 is amended to clarify that the virus is inactivated.

3. Claims 2, 5, 6, 8, 9, 13, 14, 16, 18, 23, 26, and 30

The Examiner objected to the language "the virus" for antecedent basis. As noted above, claim 1, from which claims 2, 5, 6, 8, 9, 13, 14, 16, 18, 23, 26, and 30 depend, is amended to provides proper antecedent basis for the language. Specifically, claim 1 recites a native virus envelope from a virus...where the virus is inactivated.

Thus, it is clear that the exogenous gene is encapsulated in an inactivated, native virus envelope.

4. Claim 9

The Examiner objected to the language "detergent is octylglucosidase" for antecedent basis. Applicants have amended claim 9 to correct a typographical error and correctly recite "detergent is octylglucoside." Applicant respectfully submits that the language finds proper antecedent basis in claim 8, from which claim 9 depends.

5. Claims 18 and 30

The Examiner objected to the claims as allegedly incomplete for omitting essential structural cooperative relationships of elements. Specifically, the Examiner states that the omitted structural relationships are preparing the gene transfer vector. Claim 18 is amended to recite the steps of preparing the gene transfer vector.

In light of these remarks and amendments, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

III. Rejection under 35 U.S.C. §102

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 23, and 26 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Epstein *et al.* (U.S. Patent No. 6,183,752).

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 18, 23, 26, and 30 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Altieri *et al.* (U.S. Patent No. 6,509,162).

Claims 1, 2, 5, 6, 8, 9, 11, 12, 13, 14, 18, 23, 26, and 30 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Fong *et al.* (U.S. Patent No. 6,051,428).

A. The Present Claims

The present claims relate to a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope (claim 1); a pharmaceutical composition comprising the gene transfer vector (claim 13); a kit for screening gene

libraries comprising the gene transfer vector (claim 14); a method for preparing the gene transfer vector (claim 16); and a method for introducing a gene into an isolated animal tissue with the gene transfer vector (claim 18).

B. The Cited References

EPSTEIN ET AL. describe compositions and methods for therapy and/or prevention of restenosis and/or decreasing viral load of cytomegalovirus.

ALTIERI ET AL. relate to methods and compositions for use in identifying agents that modulate the phosphorylation of surviving, the interaction between surviving and $p34^{cdc2}$ cyclin B1 kinase complex, and the interaction between surviving and caspase-9.

FONG ET AL. disclose an autologous vaccine produced by transducing tumor cells with a herpes simplex virus amplicon containing the gene for an immunomodulatory protein.

C. Analysis

1. Rejection over Epstein *et al.*

Epstein *et al.* fail to teach a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope, wherein the virus is inactivated. As described in Col. 1, lines 37-49 the antigen can be derived by expression in a replication-deficient herpes virus vector. Nowhere do Epstein *et al.* describe a native virus envelope where the virus is inactivated as presently claimed. Instead, the expression system of Epstein *et al.* may include a replication-deficient, not inactivated vector. Nor do Epstein *et al.* provide any guidance beyond this simple description. Epstein *et al.* state that antioxidants or anti-viral agents inhibit replication of a virus; however, this inhibition does not include, or even suggest, inactivation. This inhibition is merely due to repression of growth. As such, vectors treated with antioxidants or anti-viral agents are not even truly replication-deficient.

2. Rejection over Altieri *et al.*

Altieri *et al.* fail to teach a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope, wherein the virus is inactivated. As described in Col. 19, lines 63-67 viral vectors and replication-defective viral vectors have been used to transduce cells. Included are herpes viral vectors. However, nowhere does Altieri *et al.* describe a native virus envelope where the virus is inactivated. Instead, the Altieri *et al.* describe a replication-deficient, not inactivated vector. Nor does Altieri *et al.* provide any guidance beyond this simple description.

3. Rejection over Fong *et al.*

Fong *et al.* fail to make any mention of a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope, wherein the virus is inactivated. As described in Col. 1, lines 63-67 tumor cells may be transduced with a herpes simplex virus amplicon. However, nowhere does Fong *et al.* describe a native virus envelope where the virus is inactivated. Further, Fong *et al.* describe a replication defective HSV amplicon vector (see Col. 5, lines 63-64). At Col. 6, lines 1-2, Fong *et al.* reference Geller and Breakfield (*Science*, 241:1667-1669, 1988) as the HSV amplicon vector. As seen in the article, copy enclosed, the HSV amplicon as described in Fong *et al.* is not inactivated as presently claimed.

Additionally, it is asserted that Fong *et al.* teach administering Triton X-100 to an isolated cell infected with the replication defective herpes virus. A careful reading of the Fong *et al.* reference shows that the detergent was added to cultured cells to lyse the target cells. In contrast, as presently claimed, the gene transfer vector is prepared by a method which comprises a step of mixing the virus with an exogenous gene in the presence of a detergent such as Triton X-100. Therefore, the recitation of Triton X-100 as a detergent for lysing cells as in Fong *et al.* cannot be used to anticipate the presently claimed vector.

As the cited references fail to teach each of the claimed elements, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §102.

Applicants further enclose herewith a Terminal Disclaimer executed by Ei Yamada, an officer of the Assignee of the entire right, title and interest to replace the Terminal Disclaimer filed on May 1, 2006.

Accordingly, Applicant respectfully submits that the claims now pending are in condition for allowance. Therefore, a Notice of Allowance is respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,

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